

REMARKS/ARGUMENTS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 27-34 are pending in the present application. Claims 19-26 have been rejected. New claims 27-34 have been added.

In the outstanding Official Action, claims 22, 24 and 26 were rejected under 35 USC 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, with which it is most nearly connected, to make and/or use the invention. Applicants believe that the present amendment obviates this rejection.

In imposing the rejection, the Official Action alleged that the specification was not an enabling disclosure to transform a plant while targeting a transgene to a genomic region where an artificial male sterility (AMS) gene is already present. The Official Action alleged that while a transformation with a construct that comprises both the transgene and an AMS is enabled, targeted transformation such that a transgene is transformed to an AMS already present in a plant is not enabled (see Official Action, page 3).

Applicants maintain that the production of a plant carrying a cytoplasmic male sterility gene can be readily achieved by one skilled in the art. As stated in the amendment of March 20, 2003, applicants believe that the present specification, in view of the general knowledge in the field of plant transformation, provides sufficient guidance to enable one skilled in the art to transform a plant with a transgene and carry out the claimed method.

Indeed, while the Official Action points out the number and type of examples provided in the specification, the Official Action still fails to address or provide evidence as to why one of ordinary skill in the art would not be able to conduct the claimed method in view of the teachings of the present specification and the level of skill and knowledge possessed by one ordinary skill in the art.

Nevertheless, in the interest of advancing prosecution, previous claims 19-26 have been canceled and new claims 27-32 have been added. In particular, the Examiner's attention respectfully directed to new claim 29. New claims 29 recites that the plant is transformed with a plasmid vector that contains both the (AMS) gene and the transgene of interest. Indeed, applicants believe that claims 27-32 are enabled by the present disclosure.

Claims 19-26 were rejected under 35 USC 112, first paragraph, as allegedly being based on an insufficient written

description. Applicants believe that this rejection is moot in view of the present amendment.

Applicants believe that the recitation "said plant is cultivated for seed or fruit production" is supported by the present specification. Nevertheless, in the interest of advancing prosecution, this recitation has been removed from the claims. Thus, it is believed that this rejection has been obviated.

In the outstanding Official Action, claims 19-26 were rejected under 35 USC 112, second paragraph, as allegedly being indefinite. Applicants believe that the present amendment obviates this rejection.

In the outstanding Official Action, claims 19 and 22 were alleged to be indefinite for reciting the phrases "incorporating said transgene" and "comprising". The amendments suggested by the Examiner as regards to the previous claims 19 and 22 have been incorporated in new claims 27 and 29. Applicants would like to thank the Examiner for her suggestion as to how to overcome these rejections.

As to the phrase "artificial male sterility (AMS) gene", applicants believe that this phrase is definite to one of ordinary skill in the art. The Examiner's attention is respectfully directed to the present specification at page 2, lines 30-32, wherein the specification explains that male sterility can also be "artificial" that is, induced by the

expression of a gene which confers male sterility (AMS gene). A corresponding definition may be also found in VEDEL et al., cited by the Official Action. VEDEL et al. explain that male sterility can be artificially induced by transformation with an engineered chimeric gene consisting of another specific promoter associated to a MS (Male Sterility) deleterious gene (page 613). Thus, applicants believe that one of ordinary skill in the art would find the term "artificial male sterility gene" definite.

Applicants believe that the objection to the term "genetically linked" has been obviated. In particular, the Examiner's attention is directed to claim 29 which has been amended to recite that the AMS gene and the transgene of interest are carried together by a plasmid vector.

Claims 19 and 21 were rejected under 35 USC 102(b) as allegedly being anticipated by SVAB et al. Applicants believe that the present amendment obviates this rejection.

SVAB et al. discuss the prevention of transgene dissemination by transformation of a tobacco that is functionally male sterile. Applicants maintain the position that the tobacco plant disclosed in SVAB et al. fails to carry cytoplasmic male sterility and that the plant does not exhibit an AMS gene. The tobacco disclosed in SVAB et al. is functionally male sterile due to shortened filaments and are capable of producing viable pollen

by hand pollination to obtain seeds (see page 8526, right column).

Nevertheless, the Examiner's attention is respectfully directed to claims 27, 30 and 34 which provide that the plant is selected from the group consisting of maize, rape and tomato. Thus, it is believed that this rejection has been obviated. Moreover, applicants note that SVAB et al. do not teach a method for preventing the dissemination of a transgene encoding a therapeutic or prophylactic compound of human or animal origin wherein the plant is transformed with a plasmid vector containing an artificial male sterility (AMS) gene and a transcription terminator.

Thus, it is believed that SVAB et al. fail to anticipate or render obvious the claimed invention.

In the outstanding Official Action, claims 19 and 21 were rejected under 35 USC 102(e) as allegedly being anticipated by MALIGA et al. It is believed that the present amendment obviates this rejection.

MALIGA et al. is directed to the transformation of a tobacco that is also functionally male sterile. Applicants also believe that MALIGA et al. disclose transformation of a tobacco that is functionally male sterile due to shortened filaments. As noted above, claims 27, 30 and 34 recite a plant which is selected from the group consisting of maize, rape, and tomato. Thus,

applicants believe that MALIGA et al fail to anticipate or render obvious these claims.

Likewise, applicants believe that the publication fails to teach a method for preventing the dissemination of a transgene encoding a therapeutic or prophylactic compound of human or animal origin wherein the plant is transformed with a plasmid vector containing an artificial male sterility (AMS) gene and a transcription terminator.

Thus, it is believed that MALIGA et al fail to disclose or suggest the claimed invention.

Claims 22-24 were rejected under 35 USC 102(b) as allegedly being anticipated by JORGENSEN. Applicants believe that this rejection has been rendered moot by the present amendment.

Applicants believe that JORGENSEN discloses a method for producing transgenic plants with a marker closely linked to a nuclear male sterile locus. Applicants believe that JORGENSEN fails to disclose or suggest transforming a plant with a transgene and an AMS gene at the same time. Moreover, applicants believe that the broad construction of the term "genetically linked" does not correspond with the definition set forth in the specification. Indeed, the Examiner's attention is respectfully directed to the present specification at page 3, lines 26-32, wherein the specification refers to a genetic distance which is

sufficiently short for the frequencies of recombination during meiosis to be negligible. As a result, applicants believe that it is improper for the Official Action to contend that two genes are genetically linked even if they are on opposite ends of the same chromosome.

Thus, applicants believe that JORGENSEN fails to anticipate or render obvious the claimed invention.

Claims 22-24 were rejected under 35 USC 102(b) as allegedly being anticipated by MARIANI et al. This rejection is respectfully traversed.

MARIANI et al. describe a fertility restorer plant and method. A plant with male sterility is crossed with a restorer plant. Applicants believe that MARIANI et al. fail to teach a method comprising transforming a plant with a plasmid vector containing an AMS gene and a transgene of interest, where both genes are genetically linked. Contrary to the Official Action's assertions, MARIANI et al. do not state that 25% of the plants are male sterile. MARIANI et al. teach that offspring of these pollinated male-sterile plants are analyzed and 75% of their flowers do not exhibit a male-sterility phenotype (column 28, lines 16-19). The viability and phenotype of the remaining 25% of the flowers described by MARIANI et al. are not even discussed. Indeed, applicants submit that the method is limited to the crossing of plants with nuclear male sterility (see column

14, lines 7 to 30) and that the progeny resulting from such a cross cannot prevent pollination.

As a result, it is believed that MARIANI et al. fail to disclose or suggest the claimed invention.

Claims 22-24 were rejected under 35 USC 102(e) as allegedly being unpatentable over FABIJANSKI et al. This rejection is respectfully traversed.

Applicants believe that FABIJANSKI et al. fail to disclose or suggest the claimed invention. FABIJANSKI et al. do not teach a method wherein the gene of interest may be a gene of human or animal origin that is of therapeutic or prophylactic interest, as recited in new claim 29. Support for this recitation may be found in the present specification at page 14, lines 22-27. Applicants believe that an antibiotic resistance gene can not be regarded as a transgene that encodes for a therapeutic or prophylactic compound of human or animal origin.

Thus, it is believed that FABIJANSKI et al. fail to disclose or suggest the claimed invention.

Claims 19 and 21 were rejected under 35 USC 102(b) as allegedly being anticipated by METZ et al. Applicants believe that METZ et al. fail to teach the claimed invention. METZ et al. teach a transgenic broccoli expressing an insecticidal crystal protein. However, METZ et al. fail to disclose or suggest the transformation of mace, rape or tobacco. Moreover,

applicants believe that METZ et al. fail to teach a transgene that encodes a therapeutic or prophylactic compound of human or animal origin. As a result, it is believed that METZ et al. fail to teach the claimed invention.

Claims 19 and 21-26 were rejected under 35 USC 103(a) as allegedly being unpatentable over each of D'HALLUIN et al. and METZ et al. in view of WELTER. Applicants believe that the present amendment obviates this rejection.

Applicants respectfully submit that WELTER fails to qualify as prior art. WELTER was published after the priority date of the present application. As to METZ et al., METZ et al. fail to disclose or suggest the transformation of maize, rape or tobacco. Moreover, METZ et al. fails to disclose a transgene encoding a therapeutic or prophylactic compound of human or animal origin. D'HALLUIN et al. disclose transformation of monocotyledonous plants. Applicants believe that D'HALLUIN et al. fail to disclose or suggest a transgene encoding a therapeutic or prophylactic compound of human or animal origin. In this regard, the Examiner's attention is directed to new claims 28 and 29. Thus, it is believed that the above-identified publications fail to disclose or suggest, alone or in combination with each other, the claim invention.

Claims 19-21 were rejected under 35 USC 103(a) as allegedly being unpatentable over METZ et al. in view of VEDEL et

al. Applicants believe that the present amendment obviates this rejection.

As noted above, METZ et al. is concerned with protection of plants against plant pests by transforming a plant with a gene encoding a protein with insecticidal activity. METZ et al. seeks to confer pest resistance to a plant. VEDEL et al. discuss types of male sterility. As METZ et al. are not concerned with the prevention of transgene dissemination and do not pertain to the same technical area as VEDEL et al., applicants believe that one of ordinary skill in the art would lack a motivation and a reasonable expectation of success in combining and modifying the teachings of VEDEL et al. and METZ et al. to obtain the claimed invention.

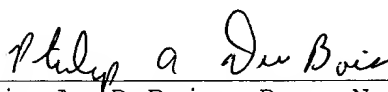
Thus, in view of the present amendment and the foregoing remarks, therefore, it is believed that this application is now in condition for allowance, with claims 27-34, as presented. Allowance and passage to issue on that basis are accordingly respectfully requested.

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Docket No. 0512-1062

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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